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Learning objectives

After completion of this self-study activity, the learner will be able to:

1. Describe how to monitor and release an implant load based on the results of the biological indicator (BI) process challenge device (test pack).
2. List the steps necessary to be able to release an implant load in an emergency situation.
3. Discuss how to document the sterilization process results of implant loads.
4. Discuss why the results of Class 5 integrating indicators do not predict 100% of the time the results of a biological indicator (BI) when there is a sterilization process failure.

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SELF-STUDY Series

No short cuts!

Monitoring implant loads

by Martha Young, BS, MS, CSPDT

This inservice will discuss the recommended practices for monitoring the sterilization of implants. It is your responsibility to follow these recommended practices and improve patient safety.

The Association for the Advancement of Medical Instrumentation's (AAMI's) newest recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006) states:

"Patient safety could be adversely affected by the implantation of a nonsterile device. The sterilization of implantables should be closely monitored and each load containing implants should be quarantined until it is verified that BI testing has yielded negative results. In defined emergency situations in which quarantine of implants cannot be maintained, breaking of the quarantine is allowed for documented medical exceptions in accordance with facility policies and procedures."¹

The Association of periOperative Registered Nurses (AORN) *Recommended Practices for Sterilization in Perioperative Practice Settings* published January, 2006 states:

"Implants are foreign bodies, and they increase the risk of surgical site infection."²

The risk to the patient when a non sterile implant is used is discussed in an article by Janet Schultz, "Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities"³:

"The mortality rate (deaths) associated with infected total hip replacements approaches 50%, from the infection itself and from the complications associated with the resulting impaired mobility, such as blood clots and pneumonia."³

Possible patient outcomes with implants include a higher degree of risk of infection because:

- "First, they are left behind at surgery, so if there are microorganisms on them, these will remain in the body. Infections associated with implants may not be evident for up to a year after surgery.
- Second, the placement of an implant often means the removal of tissue, with interruption of blood supply and significant manipulation of the tissues immediately adjacent to

the implant, creating an area of potential safety for microorganisms to multiply, further increasing the risk of infection.

- Third, because there is interrupted blood supply, antibiotics cannot easily get to the microorganisms if they do multiply enough to cause a clinical infection.
- Fourth, the implant itself may be vital to continuing function of a body system, such as would occur with a total joint replacement, vascular graft, or intraocular lens placement. An infection may not be curable with the implant in place, and removing it could cripple or kill the patient."³

When patient safety is involved, short cuts are not acceptable so read on for the "hows" of appropriately monitoring implant loads.

What is an Implant?

The Association for the Advancement of Medical Instrumentation's (AAMI's) newest recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006) defines an implant/implantable device as:

"According to FDA, "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants"[21 CFR 812.(d)].(ST79)

The preferred method for processing implants is steam sterilization using the wrapped method (unless low temperature sterilization is required). The medical device manufacturer's (MDM) instructions for use must be followed to ensure that you use enough time at temperature to achieve sterilization.

The AORN 2006 recommended practices says to use flash sterilization only when there is insufficient time to process by the preferred wrapped or container method and that the flash method should not be used as a substitute for insufficient instrument inventory.²

See "Sterilization of Surgical implants: Did You Know" authored by Rose Seavey⁴ for more details on implant sterilization.

Implantable Devices Load Record										
Date	Description of implants	Dept.	Time sterilized (specify AM/PM)	Sterilizer #	Load #	Date/time BI in incubator	Date/time and BI result	Early release?	Date/time released to OR	Released by (full name)

Figure L.1 Example of documentation of premature release of implants Devices Load⁸
 Provides an Implantable Devices Load Record and an Exception Form for Premature Release of Implantable Device/Tray, as examples of the forms recommended in Section 10.5.3.3.

Monitoring of Implant Loads

All sterilization monitoring tools should be used to monitor implant loads with the final decision to release the load based on the results of a biological indicator.

- physically monitor each load;
- label every package with an external process indicator;
- every package should contain an internal CI;
- a PCD [process challenge device (test pack)] containing a BI and a Class 5 integrating CI or an enzyme-only indicator should be used in each load containing an implant.¹

The sterilizer operator should review the physical monitors and results of other indicators to determine if the results are appropriate. If not, the load should be reprocessed. However, even if the results are acceptable, “the load should be quarantined until the results of the BI testing are available (CDC, 2003a).”¹ Documentation and release of loads in emergency situations is discussed in the Documentation section of this inservice.

The 2006 AORN recommended practices requires the use of the same monitoring tools as AAMI ST79 for monitoring implant loads. In addition AORN states:

“Flash sterilization should not be used for implantable devices. Implants are foreign bodies, and they increase the risk of surgical site infections. Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices. When an implantable device is sterilized at a health care facility, a biological indicator should be run with the load and the implant should be quarantined until the results of the biological indicator are known. If an emergency situation makes flash sterilization unavoidable, a rapid-action biological monitoring device should be used along with a class V chemical integrator. The implant should not be released until the rapid-action indicator provides a negative result. After the rapid-action negative result is obtained, the implant can be released for use in the immediate situation. If the implant is not used, it cannot be saved as sterile for future use. Resterilization of the device is required. If the biological indicator is later determined to have a posi-

tive result, the surgeon should be notified as soon as the results are known.”²

Ramona Connor, RN, MSN, CNOR, who currently represents AORN on the AAMI Sterilization Standards Committee, clarified how to quarantine a flashed implant to maintain the sterility while awaiting the results of the rapid-action biological monitoring devices (BI with enzyme-based early-readout). She stated, “The sterilized implant can be placed on a corner of the back table and segregated from the rest of the sterile field until the rapid-readout BI is ready to read. When the BI result is negative, then the implant can be placed in the patient. If the BI is positive, the implant hasn’t been used and the rest of the sterile field hasn’t been contaminated.”

The AORN recommended practice guidance is not to flash sterilize implants because:

“Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process. It is essential that all steps in the sterilization process be performed in a conscientious manner.”²

Documentation of Implant Loads

AAMI ST79, 2006 states:

“Documentation ensures that the sterilization process is monitored as it is occurring, ensures that cycle parameters have been met, and establishes accountability.”¹

Lot control numbers

Each item or pack should be labeled with a lot control identifier (sterilizer identification number or code, date of sterilization and cycle number).

“Ideally, every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted; such traceability can be accomplished by recording the sterilizer load identifier on the patient chart or the patient name on the load record.”¹

For flash sterilization, labels are not used but the following information should be generated for each sterilization cycle using a load record:

- sterilizer identification and cycle number;
- contents of load;
- time and temperature of exposure phase of cycle;
- signature or identification of operator;

- date and time of cycle.

Sterilizer records

As with any sterilization cycle, the following sterilizer records must be maintained for each load:

- lot number;
- contents of load;
- exposure time and temperature if not on a recording chart;
- operator identification;
- results of BI testing;
- results of the Bowie-Dick testing;
- results of chemical indicator (CI) in the PCD (BI challenge test pack, BI challenge test tray, CI challenge test pack);
- any reports of inconclusive or non responsive CIs in the load.¹

AORN in general recommends the same documentation of implant loads.²

Expiration dating

For proper stock rotation each item should be labeled with an expiration date.

“Each item in a load should be labeled with a control date for stock rotation and the following statement (or its equivalent): “Contents sterile unless package is open or damaged. Please check before using.”¹

Premature releasing of implants

AAMI ST79 2006 requires the following documentation if a medical exception requires the release of an implant before the BI results are known.

“When medical exceptions dictate (e.g., the need for trauma-related orthopedic screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. (See Figures L.1 and L.2 for examples of an implant log and exception form.) It is critical that this documentation be fully traceable to the patient. **Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule. Emergency situations should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management.**

See *SELF-STUDY* on page 38

Answers	1. A
	2. A
	3. A
	4. A
	5. A
	6. A
	7. A
	8. A
	9. A
	10. A

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Steps should be taken to reduce the frequency of emergency release of implantable items. For example, ongoing periodic reviews of the exception forms and implant logs could reveal consistent patterns of events that are causing emergency release and that could be corrected.⁷¹

Premature release of implants before the BI result is available is unacceptable, should be the exception not the rule and each exception should be documented using an implant exception form. This form (see Figure L.2 below) requires providing the following information each time an implant is prematurely released:

- Name of:
 - o Implant prematurely released;
 - o Patient;
 - o Surgeon.
- Reason for premature release;
- What could have prevented premature release of the implant.

AORN documentation for flash sterilized implants says that the flashed implant should be traceable to each patient:

- Information on each load should include
 - o Device(s) processed
(exact name of instrument)

- o Patient receiving item(s)
- o Reason for flash sterilization²

All the documentation needed to prematurely release implants before the BI is available or for flash sterilization of implants is to provide information to assist the health care facility in eliminating these situations which effect patient safety.

Biological Indicators vs Class 5 Integrating Indicators

The 2006 AAMI ST79 and AORN recommended practices are very clear that releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.^(1,2) Emergency situations should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management. An emergency situation is not lack of inventory or because you cannot wait for the BI results. Enzyme-based early-readout BIs with a 1 or 3 hour readout have been on the market for over 16 years and are successfully used to release implant loads with the least amount of quarantine time. The enzyme-based early-readout BI (rapid action biological monitoring device) is the BI of choice for monitoring flash sterilized implants

in the AORN recommended practices. AAMI recommended practices discuss the use of both enzyme-based early-readout and conventional BIs.

AAMI ST79, 2006 is very clear about why Class 5 integrating indicators cannot be used as a replacement for BIs:

“Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilizer cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities

should also be conducted using BIs. In addition, Garner and Favero (1985) and CDC (2003a) recommend routine biological monitoring of sterilizer efficacy. **While the performance of Class 5 integrating CIs and enzyme-only indicators has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle;** however, they provide additional information about the attainment of the critical parameters of the sterilization process.⁷¹

In addition, based on the outdated Association for the Advancement of Medical Instrumentation (ANSI/AAMI ST60:1996) *Chemical indicators-Guidance for selection, use and interpretation of results* document, the Class 5 integrating indicators response only needs to correlate to the performance of a BI at one time and temperature condition and this is with ideal saturated steam.⁵ In the new standard, ANSI/AAMI/ISO 11140-1 2005 *Sterilization of health care products-Chemical indicators-Part 1: General requirements*, testing under ideal conditions of saturated steam at three time and temperatures are required and the stated value at 250°F/121°C must be greater than 16.5 minutes.⁶ But none of this testing by the manufacturer requires that the Class 5 integrating indicator results agree with the BI 100% of the time, particularly when there are sterilization process failures.

Recent scientific studies have demonstrated that failures, due to marginal cycle conditions created by either inadequate air removal or with superheated steam conditions, were not detected equally by chemical and biological indicators.⁷ Under these common cycle failure conditions all BIs tested, which included spore strips, self-contained BIs and Rapid Readout BIs (enzyme-based early-readout BIs), detected the cycle failures. Integrating indicators, however, failed to detect the same cycle failure conditions in side-by-side testing. The conclusions reached were that only biological indicators consistently detected all of the sterilization process failure conditions evaluated and that both the fluorescent readout (enzyme-based early-readout) and visual readings detected the failure conditions.

Biological indicators (enzyme-based early readout or visual response) are the gold standard for determining the lethality or efficacy of a sterilization process. Class 5 integrating indicators do not predict or agree with the BI results 100% of the time in sterilization process failures. In fact there is no data to show 100% agreement with BIs in ideal saturated steam sterilization processes, only at one time

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES: _____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE/TRAY? _____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

Figure L.2

Exception form for premature release of implantable device/tray⁸

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. O.R. personnel should complete this form and return it to Central Service within 24 hours.

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and temperature. Using Class 5 integrating indicators to release implants is an unacceptable short cut.

Summary

The 2006 AAMI and AORN recommended practice state that an implant should be quarantined until the BI result is negative. Because:

“Biological indicators are the only sterilization process monitoring device that provides a direct measure of the lethality of the process.”¹

“Patient safety could be adversely affected by the implantation of a nonsterile device.”¹

In addition:

“Accountability to the patient and surgeon for the sterility of a reprocessed device requires documentation that can be directly traced to the patient. Traceability of implants is especially important because the consequences of implant-related infections are particularly severe and result in increased morbidity and mortality.”¹

AORN says “Flash sterilization should not be used for implantable devices.”²

When processing implant loads, there are no short cuts. Follow the very clear AAMI and AORN recommended practices. Sleeping at night will be much easier. **HPN**

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1. Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST9: 2006.
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7. Schneider, Phil, et.al. Performance of Various Steam Sterilization Indicators Under Optimum and Sub-Optimum Exposure Conditions, in Disinfection. American Journal of Infection Control. Supplement 2, Vol. 33, No. 2, June:2005.
8. Reprinted with permission from AAMI.

Circle the one correct answer

1. Implants are foreign bodies that increase the risk of surgical site infection.
A. True
B. False
2. Flash sterilization should not be used as a substitute for lack of inventory.
A. True
B. False
3. An implant should be quarantined until the results of the BI are available.
A. True
B. False
4. An implant that is flash sterilized should not be released for use until the rapid-action BI result is available.
A. True
B. False
5. An implant should be fully traceable to the patient on who it is used or in whom it is implanted.
A. True
B. False
6. When defined medical exceptions dictate, an implant can be released prior to the BI results by reading the results of other monitoring tools.
A. True
B. False
7. Documentation of premature release of implants should include the implant prematurely released, patient and surgeon name, reason for premature release and what could have prevented premature release of the implant.
A. True
B. False
8. BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process.
A. True
B. False
9. Class 5 chemical integrator results do not agree with the BI results 100% of the time in ideal saturated steam cycle conditions or sterilization process failures.
A. True
B. False
10. Patient safety could be adversely affected by the implantation of a non sterile device.
A. True
B. False

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